

Docket numbers

2020-0043

2020-0044

UNITED STATES CENTER FOR DISEASE CONTROL

In re Matter of

Emerging Infections Program Tracking of SARS-CoV-2 Infections among Healthcare Personnel
2020-10410

In re Matter of

Investigation of SARS-CoV-2 Seroprevalence and Factors Associated with Seropositivity in a
Community Setting

BRIEF OF THEO ALLEN - INTERVENER / PETITIONER

Pro Se

Introduction

In two related dockets, the United States Center for Disease Control (CDC) seeks among healthcare personnel and the general population the infection rates and factors that are associated with getting infected. For the general population, the CDC is looking at positive antibody test rates, while for healthcare personnel, the CDC is looking at usage of personal protective equipment (PPE).

The proposed studies¹ being proposed by the CDC are unnecessary, and the information collected will have no practical utility for the purposes being considered by the CDC. Instead, the CDC, along with State and Territorial governments and other Federal Agencies should take immediate action to stop the spread of coronavirus through issuing orders requiring the proper use of PPE by all Americans, and upon speedy adoption, should strictly enforce compliance with such orders.

I. Disease spread

A. Introduction

America and the world are facing a pandemic that at this point is universally known. Among viruses, in the family of Coronaviridae, there is a subfamily of coronaviruses. This subfamily contains several viruses that have caused pandemic responses in humans, including the Severe Acute Respiratory Syndrome-1 (SARS-COV-1) discovered in 2002,² Middle Eastern Respiratory System (MERS-COV) discovered in 2012, and Severe Acute Respiratory Syndrome-2 (SARS-COV-2) which is the current pandemic.

The question that people should start to ask is how SARS-COV-2 enters the body. The enzyme that SARS-COV-2 uses to enter cells is angiotensin I converting enzyme 2 (ACE2)³. What matters for the purposes of these studies is that the enzymes are found on the cells in the nasal or respiratory system.⁴ Based on these facts, we know that the virus enters through the pathways into the nose and mouth.

We know that many people are asymptomatic, but unlike SARS-COV-1, the virus symptoms appear presymptomatic and the virus can spread by asymptomatic transmission. Studies have found this to be as high as 45% of cases⁵ However, one key is that when a person is

¹ While other studies will be recommended, they are not germane to what the agency is seeking to do.

² This virus has not been found since 2004.

³ Ge X.Y., Li J.L., Yang X.L., Chmura A.A., Zhu G., Epstein J.H., et al: Isolation and characterization of a bat SARS-like coronavirus that uses the ACE2 receptor. *Nature* 2013; 503: pp. 535-538

⁴ Needless to say that this is rudimentary, and that others are finding out more about this virus.

⁵ Daniel P. Oran, Eric J. Topol. Prevalence of Asymptomatic SARS-CoV-2 Infection. *Annals of Internal Medicine*, 2020; DOI: 10.7326/M20-3012

newly infectious, it is thought that 99⁶% of cases⁷ would not become symptomatic and would clear the incubation period after fourteen days.

B. Aerosol Transmission

Knowing that we spread through the nose and mouth, but that the healthcare industry has traditionally associated 5 μ m as a dividing line between aerosol and droplets. While the ability for the droplets to be suspended is clear, the physics and biochemistry in dentistry, which notes that up to 50 μ m may be sufficient for a droplet to stay in the air⁸ for some time.

It is thought by some that wearing a mask by an infectious person makes a difference based on this chart, assuming Person A is susceptible to coronavirus.

	Person B unmasked	Person B masked
Person A unmasked	100%	70%
Person A masked	5%	1.5%

While these numbers have been deemed false by a Reuter's Fact Claim⁹. The difference between Person B unmasked and Person B masked is 30% if Person A is unmasked but 70% if masked. The difference for Person A is 95% if Person B is unmasked but 98% if masked. The numbers need to be validated by a proper clinical trial, but regardless, these popular estimates are very significant. However, on second thought, seeing how COVID-19 spreads, the numbers appear quite reasonable.

The first fact is that this tends to support an aerosol / droplet based transmission as likely, Looking at the definition of close contact, which is about 6 feet for about 15 minutes, we can presume that the droplets can stay in the air for about fifteen minutes before falling to the ground. Based on this sort of data, the droplets are no larger than 10 μ m and are able to spread the

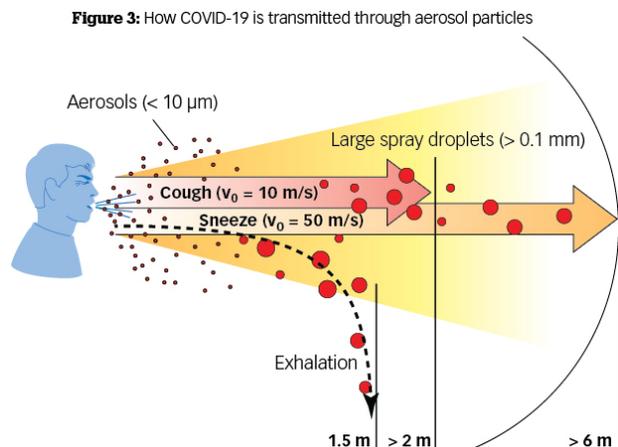
⁶ The numbers given are 101 out of 10000

⁷ Stephen A. Lauer, MS, PhD, Kyra H. Grantz, BA, Qifang Bi, MHS, Forrest K. Jones, MPH, Qulu Zheng, MHS, Hannah R. Meredith, PhD, Andrew S. Azman, PhD, Nicholas G. Reich, PhD, Justin Lessler, PhD: The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. 5 May 2013: <https://www.acpjournals.org/doi/10.7326/M20-0504>.

⁸ [https://jada.ada.org/article/S0002-8177\(14\)61227-7/pdf](https://jada.ada.org/article/S0002-8177(14)61227-7/pdf) (April 2004, STEPHEN K. HARREL, D.D.S.; JOHN MOLINARI, Ph.D)

⁹ <https://www.reuters.com/article/uk-factcheck-coronavirus-mask-efficacy/partly-false-claim-wear-a-face-mask-covid-19-risk-reduced-by-up-to-98-5-idUSKCN2252T6>

disease¹⁰. The evidence tends to be confirmed by dental studies. Since an aerosol's ability to suspend in the air is related to weight and size, but not the RNA coding, the aerosols have identical properties and tend to stay in the air.



Based on this chart, sneezing or coughing are major risks.¹¹ It should be clear that coughing or sneezing is a major risk which occurs both indoors and outdoors.

In addition, when engaging in heavy breathing, such as vigorous exercise, shouting, singing, or even talking, there is a need for greater air flow. Such activities, however, cause a greater amount of virus to spread as a person is exhausting a greater number of droplets.

A person, when they breathe out, gives away droplets, of varying sizes. When a person breathes out, the air is exhausted and is spread in a cloud of primarily droplets. The droplets fall to the ground, and some will evaporate, which makes the droplet parts lighter and makes suspension in the air easier. Those droplets can be inhaled by the forces of breathing, which pulls the same amount of air in as is exhausted, although not in the same direction, which for exhaustion is largely straight out.

C. Environmental Factors

Since the droplets float or are suspended in the air, they float freely near where a person breathes. A way to look at this issue is how carbon dioxide works in space. On the Space Station, astronauts have to be aware of air pockets due to the lack of circulation. If the air didn't circulate,

¹⁰ https://static1.squarespace.com/static/5c31336370e802d27733696e/t/5eebe610bbd95d4c1ad651f0/1592518163193/RWI_Why+Masks+Should+Be+Mandatory.pdf [Run With It Synthetics]

¹¹ <https://www.perioimplantadvisory.com/periodontics/oral-medicine-anesthetics-and-oral-systemic-connection/article/14173521/covid19-and-the-problem-with-dental-aerosols> (Scott Froum, DDSMichelle Strange, MSDH, RDH Apr 7th, 2020)

astronauts would have in ten minutes too much carbon dioxide. For that reason, there has to be strong filtration systems in spacesuits and any spacecraft.¹²

This circulation means that the filters can get dirty and carbon dioxide filters are needed. As seen on Apollo 13, mission control had to rush to figure out how to get new CO₂ filters into Aquarius¹³ because there is a lack of circulation. So we know that once we breathe in or out, excluding the force of gravity, the air wants to stay in one place. But outside, this does not happen.

Any air circulation system has to, by using energy, such in the air in a given location. The inside air has to be mixed with outside air, which has to be heated or cooled to room temperature, using much energy. The air also needs to be filtered for pollutants, like viruses, bacteria, dust, or pollen. In a positive or negative pressure environment, the job is tougher because you have to forcibly pump or more air opposite the direction the air wishes to flow, from high pressure to low pressure. To reduce transmission indoors, you need to frequently have the air be either replaced with air from the outside or go through the air and filter it from aerosols like SARS-COV-2.

D. Personal Protective Equipment.

PPE comes in various forms, but for arguments, I will discuss equipment that protects by categorizing the equipment.

1. Face covering

By wearing a face covering properly, you ensure that your droplets contact the mask. This prevents aerosolization of these droplets, and sharply limited exposure. In order to be effective, it needs to fit snugly around the nose and mouth tightly to the skin. It also needs to have no holes greater than about 5 microns, so it can be a tightly machine manufactured cloth mask, although for efficiency, three layers of different materials are recommended.

A face mask with a valve, hole, or similar filtration device that allows air to escape from the valve. While such a mask can be a respirator, it is not a face covering and needs to be covered. Due to the distance from the nose and mouth, the mask needs to be covered by a surgical mask to be effective unless it has two way filtration.

2. Respirator

Due to the pressure of breathing in, a respirator needs to have a seal which ensures that all particles have to travel through the mask and cannot come in on the outside of the mask. While a cloth or procedural mask is a face covering, most respirators need to be tightly fitted.

¹² <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.694.8269&rep=rep1&type=pdf>
In-Flight Carbon Dioxide Exposures and Related Symptoms: Association, Susceptibility, and Operational Implications

¹³ Link to transcript of radio calls can be found at https://www.hq.nasa.gov/alsj/a13/a13_LIOH_Adapter.html

However, based on the definition of a respirator that I define, the term is not limited to an N95 mask.

While a respirator loops around the head normally, that is not a requirement. The requirement is that facial movements do not modify the seal the mask has. Some examples on how a respirator can be formed are listed below.¹⁴

A surgical mask with a do it yourself elastic tool, such as a rubber band chain or a surgical mask brace, if it meets the requirements of getting a seal fitted, would qualify as a respirator¹⁵. Something which may force the air out a different way, such as a snorkeling mask, provided there is a seal and the mask is covered by a filter which has a seal or is otherwise attached to the mask and filters to the level required for any respirator. A gas mask which prevents tear gas from entering would likely qualify as a respirator. This explicitly includes gas masks used by the Department of Defense against chemical and biological warfare¹⁶.

3. Face shield

A face shield is something that blocks the flow of air through it. A face shield needs to be tied to the head and goes in front of, covering the face while allowing free airflow from the sides and bottom.

4. Reduction

Based on various studies, the amount which universal masking would reduce the rate of transmission and viral load is subject to debate. However, whether the rate of transmission drops 50% or 90% should not make a difference. The CDC Deputy Director has stated “We have way too much virus across the country for that right now, so it’s very discouraging.” Secretary Azar has declared “the window is closing”.

It is always possible to do what Governor Lujan Grisholm did in shutting down Gallup, New Mexico for ten days. But if people wore masks universally, I do not believe we would need it. For these reasons, I ask the CDC to take immediate action with others to issue the following mandates.

II. Standard for PPE

The CDC should apply one uniform standard for personal protective equipment. This should be based on the current tuberculosis standard. Outside, there is insignificant likelihood of

¹⁴ These are possible suggestions on possible respirators. The author has made no effort to determine whether the National Institute for Occupational Safety and Health Administration has certified the mask as a respirator.

¹⁵ This has been proposed by “Fix the Mask”. The website is www.fixthemask.com but the author declines to certify its accuracy. The author has attempted unsuccessful such solutions to his mask.

¹⁶ It should not be missed that we are fighting a biological war against SARS-COV-2.

spread by aerosols, so if a person is unable to maintain six feet from another (other than someone they live with¹⁷), they should be required to wear a face shield, mask, or respirator.

Based on masks working to protect others when working properly, indoors, in any public place, everyone should be required to wear a face covering properly. As a consequence, indoor dining should be prohibited. In a case where a person is forced to share a room¹⁸ with another, and that person cannot or is not wearing a face covering, a respirator should be required. Vigorous activities, such as use of hymns or singing, should be avoided. In addition, personnel conducting testing for coronavirus or aerosol generating procedures (including dental work) need to wear a respirator.

To clean and disinfect an area appears not to be overly necessary. However, when a respirator is required, the area needs to be decontaminated and no one who is not wearing a respirator departs and should be permitted in unless wearing a respirator. In addition, UV light should be used to disinfect the area. Based on current science, if left empty for twenty four hours, no additional cleaning should be needed.

Finally, reuse of masks is not as big a problem as it seems, provided the mask still works. Petitioner, not having conducted or having access to scientific research, the petitioner declines to state the degree the mask must fit to in order to be effective.

III. Studies

As shown here, aerosol transmission is a very significant concern. The good news is that SARS-COV-2 is very sensitive to soap and water on surfaces, and both droplet and surface transmission may occur.¹⁹ From the evidence I have seen though, most transmission appears to be aerosol based.

A. Healthcare Workers

In docket number 2020-0043, the CDC is looking to study cases where healthcare workers get infected, describe characteristics such as clinical procedures and PPE used, and make comparisons to identify risk factors.

The study to determine whether healthcare workers are being infected should be done, but a special study should not be used. Hospitals and health care facilities can be required to report when employees test positive the same way nursing homes are required to report such data. In addition, testing, isolating, and contact tracing works, so it needs to be implemented. If a cluster is detected, further action will be required, but the CDC does not need to study some hospitals for that.

¹⁷ Due to housing arrangements, it is unlikely to restrict spread in a household to require such measure.

¹⁸ In considering room, consideration must be paid to air replacements rate and air flow, any barriers added like a curtain, and physical distance. This is not intended to be precise.

¹⁹ Interview of Professor Kimberly Prather, PhD on June 1, 2020 with CBS News

The characteristics portion can be omitted if the CDC is not focused on how the virus spread. Instead of focusing on tuberculous based strategies at the hospital, such as negative pressure rooms, requiring respirators for personnel entering a patient's room, and having air filtered outside, other strategies are being implemented. These are unnecessary.

The CDC should study ways to maximize production and reuse of PPE so that everyone is protected. Consequently, the studies proposed on protecting healthcare workers should be abandoned. The regulations do not comply with the requirements of the Paperwork Reduction Act. Instead, the CDC and other regulating bodies should proceed to emergency rulemaking to mandate specific personal protective equipment standards for healthcare workers.

B. General Public

The CDC is seeking to determine spread in communities as determined by overall SARS-CoV-2 seroprevalence; and determine factors associated with SARS-CoV-2 seropositivity among persons residing in areas with evidence of community spread. This needs to occur anyways throughout the county, and should not simply be a "study". The reasons are that we do not want herd immunity through exposure. While once a vaccine is approved, people need to be quickly vaccinated, we need to know where the virus is.

Such a factors test should be coordinated for the purpose of seeking convalescent plasma, one of the treatments given under emergency use authorization. In addition, the demographic data on racial disparities and similar demographics is important, but not for what the agency is looking at. We know racial disparities exist and need to be addressed, but the CDC has already declared we have "way too much virus" to control the pandemic. Consequently, the studies proposed do not comply with the requirements of the Paperwork Reduction Act.

IV. OSHA

In lieu of conducting a study on personal protective equipment and factors, and in lieu of a study on how the public gets infected, the CDC should take immediately take action by asking Secretary Azar, who has declared the window is closing, to ensure the window does not close by requesting the Secretary of Labor, Eugene Scalia, to pursuant to section 655(c) of title 29, to issue an emergency order to implement my recommendations.

/s/ Theo Allen
Theo Allen

Resume

Theo Allen

Education

BS Applied Math, C.S. Minor | NYU Tandon School of Engineering Jan 2020
New York, NY

- Mastered fourth level Calculus
- Developed problem solving and analytical skills on various assignments
- Ran data analytics on scientific and statistical data
- Ran experimental data regression analysis
- Skilled in computer graphing

Software Proficiencies

- C++
- Python
- Java
- Html
- Microsoft Office

Disclaimers

This should not be treated as a guide for clinical trials, and does not constitute or replace clinical trials. It should not be used to diagnose, treat, or cure any virus, but can be used to prevent infection from coronavirus and other respiratory viruses. There has been no peer review at the time of the submission and the brief has not been submitted for peer review.

I understand that pursuant to title 42 U.S.C. §282(j), all clinical trials must be registered pursuant to title 42 C.F.R. §11.28 on www.clinicaltrials.gov. This is, not a clinical trial pursuant to 42 U.S.C. §282(j). Because cloth face coverings are not regulated devices, they are not subject to registration. While an N95 respirator and surgical masks constitute devices under 42 U.S.C. §328(h), the author declines to establish a control group to evaluate relative effectiveness.

Even if a clinical trial was possible, such a control group would be unethical to create because exposing people to less than adequate PPE would cause a grave risk of spreading the coronavirus and would not be a blind or double blind trial, insofar as the workers would know the level of PPE they possessed.

The author did not receive any payments or solicit compensation in any form for this brief. The author has a financial interest in that the author is actively seeking employment and intends to reject or resign from employment offers that the author believes do not adequately protect him from the dangers of SARS-COV-2 which would have a substantial likelihood of hospitalization and permanent damage to petitioners body, and is convinced at this time that the standards being proposed here would adequate reduce the risk to the petitioner and every American of being infected with coronavirus.